# User Requirement Specification (URS) - Laboratory Information Management System (LIMS)

## 1. Introduction

This document outlines the user requirements for a Laboratory Information Management System (LIMS) in a pharmaceutical setting.

## 2. System Overview

The LIMS will facilitate sample tracking, data management, compliance, and reporting.

## 3. User Requirements

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| --- | --- | --- |
| Requirement ID | Requirement Description | Priority |
| URS-001 | The system shall allow sample registration and tracking. | High |
| URS-002 | The system shall support electronic signatures. | High |
| URS-003 | The system shall integrate with laboratory instruments. | Medium |

## 4. Regulatory Compliance

The system must comply with FDA 21 CFR Part 11, GMP, and other regulatory standards.

## 5. Security Requirements

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| --- | --- |
| Security Feature | Description |
| User Authentication | System must support role-based access control. |
| Data Encryption | All sensitive data must be encrypted. |